II. 510(k) Summary

K110690

MAR 2 8 2012

510(k) SUMMARY

Submitted by:

ONE®
12 Channel Street
Boston, MA 02210

Contact Persons:

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Date Prepared: March 19, 2012

Propriety Name: ONE® Personal Lubricant

Proposed Trade Name: ONE® SILICONE Personal Lubricant

Common Name: Personal Lubricant

Classification Name: Condom
Class II (21 CFR §884.5300)
NUC

Predicate Device: K-Y Brand Intrigue
Personal Products Co.
510(k) No. K062796

Device Description: ONE® SILICONE Personal Lubricant is a non-sterile, personal lubricant for use with or without a condom. It is specifically formulated to be a clear, non-irritating, non-greasy and odorless, liquid. This device is not a contraceptive nor does it contain any spermicidal component. Two forms of packaging are intended. The first primary packaging (having direct contact with product) consists of a plastic packaging. The second primary packaging is foil wrappers.

Intended Use: ONE® SILICONE Personal Lubricant is an over-the-counter personal lubricant.

Indications For Use: ONE® SILICONE Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Technological Characteristics:

ONE® SILICONE Personal Lubricant contains a blend of silicone fluid ingredients similar to ingredients found in the predicate device.

Biocompatibility:

Biocompatibility testing was performed in accordance with ISO 10993-1.

Testing Performed	Results
Cytotoxicity	Product is Non-toxic
ISO Guinea Pig Maximization Sensitization Test	Product does not elicit a sensitization response
Acute Systemic Toxicity	There is no evidence of system toxicity
Vaginal Irritation and Systemic Toxicity Study Following Repeated Exposure in Rabbits (The study utilizes FDA recommended alternate design that is a hybrid between ISO Vaginal Irritation test and ISO Acute Systemic Toxicity)	Product produced no macroscopic or microscopic evidence of systemic toxicity and is considered a nonirritant.

Condom Compatibility:

Compatibility Testing was performed in accordance with ASTM D7661-10, 'Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms' on three marketed brands of Natural Rubber Latex condoms, one brand of Polyisoprene condoms, and one brand of Polyurethane condoms.

The results demonstrated that the condom compatibility testing of the silicone lubricant is compatible with commercially available male condoms made from natural rubber latex, polyurethane, and polyisoprene materials.

Shelf-Life:

ONE® SILICONE Personal Lubricant has a one-year shelf life based on the results of an accelerated aging study. The accelerated aging study evaluated both versions of packaging. The product met specifications.

A real-time aging study is being conducted to confirm results of the accelerated aging study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Sharon Pietila
Regulatory Affairs / Quality Assurance Manager
ONE
12 Channel Street
BOSTON MA 02210

MAR 28 2012

Re: K110690
Trade/Device Name: ONE® SILICONE Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: March 19, 2012
Received: March 20, 2012

Dear Ms. Pietila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VII. Indications for Use Statement

Indications for Use

510(k) Number: K110690

Device Name: ONE® SILICONE Personal Lubricant

Indications For Use:

ONE® SILICONE Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use _____ AND/OR Over-The-Counter Use ____X____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and Urological Devices

510(k) Number K110690